

### REMARKS

Claims 48, 55-59, 67, 68, 76, 77, 79, and 80 have been canceled without prejudice. Claims 45, 50, 60, 64, 65, 69, 74, 75, 78, 81 and 82 have been amended. New Claims 90-92 have been added. Support for the amendments and the new claims can be found in the Specification and claims as filed, for example, in Claims 56-59. Applicant wishes to indicate that the amendments to the claims and the arguments for their patentability are presented to put this application in condition for an appeal.

#### Double Patenting

The Examiner has rejected Claims 1-44 of the present application under 37 CFR §1.78(b) as conflicting with claims 30, 34, 40, 41, 45, and 64 of Application No. 09/582,817, and cited MPEP §822. MPEP §822 clarifies that such a rejection "should only be used when the conflicting claims are identical or conceded by applicant to be not patentably distinct." Applicants maintain that the claims are not identical. In addition, Applicants maintain that the claims are patentably distinct.

The conflicting claims are not identical. Claims 1-44 of this application drawn to a method of using a product have been withdrawn. They have been maintained in the application as they may be eligible for rejoinder upon allowance of the pending product claim 45. These claims are not identical to method claims 30, 34, 40, 41, 45 and 64 of Application No. 09/582,817. As the claims are not identical and Applicant has not conceded that the claims are not patentably distinct, Applicants respectfully request that this rejection be withdrawn.

Moreover, according to 37 CFR §1.78(b), the elimination of conflicting claims from one or more applications filed by the same applicant may be required in the "absence of good and sufficient reason for their retention" during pendency in more than one application. Applicant maintains that there are good and sufficient reasons why the claims should be retained during pendency in both applications.

As discussed above, the withdrawn claims in this application have been maintained because they may be eligible for rejoinder upon allowance of the elected claims. To be eligible for rejoinder, they must ultimately either depend from the allowed elected claims or otherwise include all of the limitations of such claims. Thus, the question of the claims 1-44 of the present application being patentably distinct from claims 30, 34, 40, 41, 45 and 64 of Application No.

09/582,817 can only be evaluated once the claims in both applications are prosecuted on the merits. In the meantime, the withdrawn claims 1-44 will not be prosecuted and there is no burden on the Examiner in having them remain in this application. Therefore, the rejection of Claims 1-44 of the present application under 37 CFR §1.78(b) should be withdrawn.

#### **Definiteness**

The Examiner has rejected Claims 48, 50, 57-60, 64-69, 74-83, 88, and 89 under 35 USC §112, second paragraph, as being indefinite. Specifically:

Claim 48 was found confusing because the expression "tracks or grooves" in Claim 45 has been interpreted as being synonyms. Claim 48 has been cancelled.

Claim 50 was found confusing as to the nature of the structural relatedness of microchannels and chambers. The Examiner suggested amending the claim to recite "which comprises microchannels and chambers wherein said microchannels fluidly connect said chambers". Claim 50 has been amended accordingly.

Claims 57, 58 and 59 were found confusing for reciting aldehyde, acrylate groups, or oxidized polymer layer on the surface of the disc prior to the binding of the capture molecules, which according to Claim 45 are already bound to said surface. Claims 57-59 have been cancelled.

Claim 60 was found confusing for reciting "upon its surface", while Claim 45 stipulates that there are at least two surfaces. Similar issues were asserted to exist with respect to Claim 64. Claim 60 has been amended to recite "upon the first specific surface", which has antecedent basis in Claim 45. Claim 64 has been amended to specify that the disc surface is a mini-CD disc surface.

Claim 65 has been found indefinite for reciting the term "specific". Claim 65 has been amended accordingly, and the term has been deleted.

Claim 66 was found indefinite for reciting that the data bytes "are present in line on the disc surface", while Claim 45 stipulates that the data in the disc's grooves and tracks, which are in a circle, not a line. Claim 66 depends on Claim 65, which recites that the disc according to the claimed invention serves as a substrate for storage information in the form of nucleic acid capture molecules, wherein the nucleic acid capture molecules correspond to data bytes. These data

bytes do not correspond to and are not the same as "registered data", and therefore can be present as a line and not necessarily in grooves of a CD/DVD.

Claim 69 was found confusing as to the relationships among "molded support", the disc, chambers, and binary data in grooves and tracks. Claim 69 has been amended to specify that the molded support divides the disc into incubation chambers, and it is in contact with a first specific surface area.

Claim 74 has been found confusing for imparting animate properties to an inanimate object by reciting that the device "allows" some process to occur. Claim 74 has been amended accordingly.

Claims 76 and 77 have been found unclear for reciting "first reading head for" and "second reading head for". Claims 76 and 77 have been canceled.

Claim 78, 79, and 81-83 have been found confusing for reciting the expression "means for". Claim 79 has been cancelled. Claims 81 and 82 have been amended accordingly. Claim 78 has been amended to specify that the second reading device comprises a photodiode.

Claim 89 has been found confusing for reciting "the surface of the disc", while Claim 45 recites multiple surfaces. Claim 89 has been amended to now recite "the first specific surface area of the disc", which has an exact antecedent in Claim 45.

In view of the amendments and cancellations, Applicant asserts that Claims 50, 60, 64-66, 69, 74, 75, 78, 81-83, 88, and 89 are now definite, and their rejection under 35 USC §112, second paragraph should be withdrawn.

#### **Written description**

The Examiner has maintained his rejection of Claims 45, 48, 50, and 52-89 under 35 USC §112, first paragraph, as allegedly failing to comply with the written description requirement. To expedite the prosecution of this application, Claims 55-59, 67, 68, 76, 77, 79, and 80 have been canceled without prejudice, therefore their specific rejections are now moot.

The Examiner again asserts that none of the "capture molecules" are impervious to any and all forms of cleavage. Applicant wishes to respectfully remind the Examiner that Claim 45 recites that capture molecules do not comprise a cleavable spacer and it does not recite capture molecules impervious to any and all forms of cleavage. Therefore, this rejection is not applicable.

The Examiner also asserts that there is not adequate written description of the immobilized nucleic acids. However, the Specification, as the Applicant argued before, provides the GenBank Accession numbers of more than 40 genes. In the recent case decided by the US Court of Appeals for the Federal Circuit (*Falkner v. Inglis*, No. 05-1324, slip op. at 16-18 (Fed. Cir. 2006)) the Court clearly stated that: "However, it is the binding precedent of this court that Eli Lilly does not set forth a per se rule that whenever a claim limitation is directed to a macromolecule sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art." "Indeed, the forced recitation of known sequences in patent disclosures would only act as unnecessary bulk to the specification. Accordingly we hold that where <...> accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences, satisfaction of the written description requirement does not require either the recitation or incorporation by reference <...> of such genes and sequences." Additionally, as the Applicant argued previously, the EP 1 136 566 publication incorporated explicitly by reference in the Specification (page 7, lines 13-17) provides additional sequences of capture molecules (on pages 10, 11, 12, and 14). Altogether, the Specification provides written description of more than 60 sequences. Thus, the Specification provides more than 60 exemplary sequences which can be attached to the claimed disks.

Furthermore, as discussed below, the methodology described in the Specification for attaching the capture molecules to the disk is effective for any nucleic acid regardless of its sequence. In addition, as discussed below, the present invention is analogous to a Southern blot in the sense that, just as any nucleic acid may be fixed to a nitrocellulose support and hybridized to target nucleic acids, any nucleic acid can be fixed to the surface of the claimed disks and hybridized to target nucleic acids. Just as one need not describe the sequences of every possible nucleic acid that can be attached to a nitrocellulose filter in order to describe a Southern blot, the written description requirement does not require one to describe the sequence of every nucleic acid that can be fixed to the claimed disks.

The Examiner stated that the Specification does not provide an example of a CD/DVD having single-stranded nucleic acid capture molecules and binary information that is to be read at the same time the hybridization results are; that the Specification does not describe a method of

performing both steps of the claimed method, a device capable of making the claimed CD/DVD or a device capable of reading it.

The Examiner also asserts that the device of Claims 74-80 encompasses a disc that can be virtually any shape, that the registered data and the capture assay may be on the same side, opposite sides or internal to the disc; that the CD may have additional coatings over the surface.

The Examiner also could not find in the Specification how a CD reader is to be manipulated to read both sides of a disc, or how to interpret the clusters of signal "when normal CD readers are interpreting pits found in grooves – which is where the registered binary data is stored".

The Examiner has also asserted that reactants well known in the art of binding of target and capture nucleic acid molecules should be listed in the disclosure.

Applicants remind the Examiner that at the recent interview (on June 14, 2006) Nathalie Zammatteo presented a demonstration of disks in which the registered data is located on a surface are of the disk distinct from that containing the capture molecules. From the demonstration it was apparent that the reading of the assay spots of the array is limited to specific areas of defined shape/surface area. The assay for the target bound to the capture molecules were present on a surface area of the disc which did not contain grooves with registered data. In that embodiment, the registered data was on the bottom surface of the disc – as on the ordinary CD with pits and grooves. The array was located on the top surface of the disc.

In addition, Ms. Zammatteo also brought a demonstration of a reading device in accordance with that described in the present application. She opened the reading device to demonstrate that it had two readers: the bottom one was a conventional CD reader for reading of the registered binary data, and the top one comprised a laser connected to a motor and a photodiode for reading of the assay spots of the array. Indeed, as asserted in the Declaration filed under 37 CFR §1.132 by Joel Demarteau submitted herewith, from the Specification it is clear to the person skilled in the art of engineering and electronics that the first reading device according to the invention is a standard CD reading device already in use for many years as of December 1997. This reading device is modified by the addition of a second reading device (such as a photodiode) which is used for the reading of the signal resulting from the binding between a target and a capture molecule. As set forth in the accompanying Declaration of Joel

Demarteau, the second reader employs standard components and can readily be assembled by those skilled in the art based on the disclosure in the Specification.

Furthermore, a person skilled in the art of bioassays involving detection of nucleic acid molecules by hybridization knows how to detect this signal, because the signal is a standard signal resulting from such a bioassay. The support (surface of the CD/DVD) does not modify the characteristics of such bioassay that have been already performed upon various other solid supports (such as wells, beads, filters, etc.) made of various materials (plastic, glass, metals, etc.). Applicant wishes to point to the Examiner, that this application is a novel cross-over combination of standard microarray technology with standard electronics of signal detection, and therefore would require two persons with ordinary skills in each of the arts, respectively.

According to MPEP 2164.05(b): The relative skill of those in the art refers to the skill of those in the art in relation to the subject matter to which the claimed invention pertains at the time the application was filed. Where different arts are involved in the invention, the specification is enabling if it enables persons skilled in each art to carry out the aspect of the invention applicable to their specialty. *In re Naquin*, 398 F.2d 863, 866, 158 USPQ 317, 319 (CCPA 1968).

When an invention, in its different aspects, involves distinct arts, the specification is enabling if it enables those skilled in each art, to carry out the aspect proper to their specialty. "If two distinct technologies are relevant to an invention, then the disclosure will be adequate if a person of ordinary skill in each of the two technologies could practice the invention from the disclosures." *Technicon Instruments Corp. v. Alpkem Corp.*, 664 F. Supp. 1558, 1578, 2 USPQ2d 1729, 1742 (D. Ore. 1986), *aff'd* in part, vacated in part, *rev'd* in part, 837 F. 2d 1097 (Fed. Cir. 1987) (unpublished opinion), appeal after remand, 866 F. 2d 417, 9 USPQ 2d 1540 (Fed. Cir. 1989). In *Ex parte Zechnall*, 194 USPQ 461 (Bd. App. 1973), the Board stated "appellants' disclosure must be held sufficient if it would enable a person skilled in the electronic computer art, in cooperation with a person skilled in the fuel injection art, to make and use appellants' invention." 194 USPQ at 461.

Applicant has now provided two 37 CFR §1.132 Declarations by skilled artisans in support of the sufficient written description and enablement of the claimed invention: the Declaration by Jose Remacle (skilled in the art of microarrays), filed May 23, 2005, and the presently filed Declaration by Joel Demarteau (skilled in the art of CD/DVDs and their readers).

As it is attested in 132 Declaration by Joel Demarteau, a person with an ordinary skill in the art of CD/DVD after reading the Specification would have not difficulties in following the directions in how to make and use the claimed CD/DVD as well as how to make and use the

claimed detection and/or reading device for reading the information of the claimed CD/DVD. Specifically, Joel Demarteau attests that he understood from the description in the Specification that the binary data is recorded on the disc in accordance with the conventional CD technology; that the nucleic acid molecules are attached to the disc in the areas free from the binary data (therefore, free from the tacks and grooves needed for the binary data), and therefore their binding does not impact the binary data on the disc; that the location of the microarrays may be anywhere on the disc as long as they do not impact the binary data, and therefore they may be located on the same side of the disc as the binary data, on the opposite side of the disc, or even inside the disc. The skilled artisan, such as this Declarant, also had no problem understanding that the areas of the disc designated for the binding of nucleic acids could be coated without impacting the binary data in separate areas of the disc.

As is also attested in the presently submitted Declaration, the skilled artisan understood that the inventors possessed the claimed CD/DVDs of any external shape or size having binary data recorded in one area of the disc surface and having nucleic acid molecules located in a second area which does not comprise tracks or grooves.

Furthermore, Joel Demarteau attests that he could readily build the claimed CD/DVD readers based on the detailed descriptions provided in the Specification. Based on these descriptions, it was apparent to the Declarant that the reader for reading the binary data may be those conventionally used in commercial CD/DVD readers for reading binary data, and that the device is supplemented with an additional reading device for the detection of signals from the binding of target and capture nucleic acids located on a second portion of the disc. Such additional reading device's specific design depends on the type of the signal to be detected, and it may be, for example, a photodiode. Such devices, as well as the motors for moving the light beam along one dimension so as to cover the radius of the disc were conventional for the detection of any type of the signal as of December 30, 1997, when the Provisional Application No. 60/071,726 to which this application claims priority was filed. Joel Demarteau stated that he could build the reader for the claimed CD/DVD based on the figures in the Specification.

Therefore, Applicant asserts that the Specification as filed provided written support for as well as enabled a person skilled in the art how to make and use the claimed invention.

## Enablement

The Examiner has maintained his rejection of Claims 45, 48, 50, and 52-89 under 35 USC §112, first paragraph, as allegedly non-enabled. Specifically, the Examiner repeated the same arguments already presented in the written description rejection, and added a new one with regards to alleged inherent obstacles in synthesizing oligonucleotides and hybridization process.

The arguments in support of the Applicants assertion that the claims are supported by the Specification as filed are presented above. As discussed previously, the methodology disclosed in the Specification for attaching a single stranded nucleic acid capture molecule to the disc is effective for any nucleic acid capture molecules regardless of their sequence. By analogy, just as the inventor of the Southern blot could satisfy the written description requirement for a claim to a nitrocellulose filter having a nucleic acid bound thereto without providing the sequences of all of the nucleic acids which could potentially be bound to the filter because the methodology for binding the nucleic acid to the filter is independent of the sequence of the nucleic acid, the present inventors also satisfy the written description requirement for the pending claims because the methodology for attaching the claimed types of capture molecules to the CD described in the specification is independent of the sequence or structure of the capture molecules. Furthermore, Figures 4 and 5 and paragraph [0071] provide enabling description of the disc where nucleic acids are located in a region of the disc that is void of any tracks or grooves. The same figures also show that the registered data from the CD track is read by one laser-based device, while the data from the array having nucleic acids is read by a separate reading device. During the course of the interview (on June 14, 2006), Nathalie Zammattéo had demonstrated a device for reading of a BioCD having the registered data on the bottom surface of the disc – as on the ordinary CD with pits and grooves, and the array located on the top surface of the disc. The reader was shown to have two reading devices: the bottom one was an ordinary CD-reading device for reading the registered data, while the top one was similar to OHP for reading the information from the array. At the time of the interview, the Examiner appreciated the presentation.

With regards to the alleged inherent obstacles in synthesizing oligonucleotides and hybridization process, according to MPEP 2164.01:

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the



experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Teletronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), aff'd. sub nom., *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985).

In this case, synthesizing oligonucleotides and hybridization process are standard procedures in the art of nucleic acids. Even if the results of hybridization is not 100% predictable, or even if the synthesis of oligonucleotides on the arrays can be only 99% efficient, there is no experimentation involved in either of these processes, as both techniques have been standard in the art for years before this application was filed.

For the foregoing reasons, Applicants respectfully request that the enablement rejection be withdrawn.

#### Novelty

The Examiner has rejected Claims 74 and 75 under 35 USC §102(b) as being allegedly unpatentable over USP 5,418,910 (Siegel).

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Claims 74 and 76 are not anticipated by the cited reference because the detection and/or reading device according to the invention comprise a disc as claimed in Claim 45, which comprises capture molecules bound to its surface and a second reading device for reading the signal resulting from the binding between a target and the capture molecules on the surface of said disc.

Therefore, the rejection of Claim 74 and 75 under 35 USC §102(b) should be withdrawn.

**Non-obviousness**

The Examiner has rejected Claims 45, 48, 50-56, 59-69, 71, 73-82, 84, and 88-89 under 35 USC §103(a) as being allegedly unpatentable over USP 5,922,617 (Wang et al.). Specifically, the Examiner stated that one of ordinary skill in the art would have been motivated at the time this invention was made to adopt a disc of Wang et al. for detection of any target sequence.

Firstly, Wang et al. reference is not prior art as evidenced by the Declaration filed under 37 CFR §1.131 by the inventors of this application, Dr. J. Remacle and I. Alexandre. According to the Declaration and the provided Exhibit, the present inventors had the conception date of the Bio-CD prior to the filing date of Wang et al. of November 12, 1997.

Secondly, while the US Patent 9,922,617 describes a solid substrate for attaching DNA molecules which can be shaped as a disk similar to a commercial compact disk (CD) having arrays in sectors of the disk with headers within the same sectors that describe the information about the sector number. However, nowhere in this document does Wang say that the disc described is a standard CD/DVD. Moreover, Wang et al. does not describe the claimed CD/DVD wherein the array area of the disc is separate from the area with registered binary data, or the reading device for reading the claimed CD/DVD. Therefore, Claims 45, 50, 52-54, 60-69, 71, 73-75, 78, 81, 82, 84, 88 and 89 are non-obvious over the cited reference of Wang et al., and their rejection under 35 USC §103(a) should be withdrawn.

The Examiner has rejected Claims 57, 58, 70, 72, and 87 under 35 USC §103(a) as being allegedly unpatentable over USP 5,922,617 (Wang et al.) as applied to claims 45, 48, 50-56, 59-69, 71, 73-82, 84, and 88-89 above, and further in view of Pemawansa et al. (USP 5,160,626), Fodor et al. (USP 5,800,992), Dattagupta et al. (USP 4,542,102), and Douglas (USP 5,556,748). Claims 57 and 58 have been cancelled without prejudice. As discussed above, Wang et al. is not prior art for the presently claimed invention, and none of the secondary references will change

Appl. No. : 10/035,822  
Filed : December 27, 2001

this fact. Therefore, Claims 70, 72, and 87 are non-obvious over the cited combinations of references, and their rejection under 35 USC §103(a) should be withdrawn.

#### CONCLUSION

In view of the foregoing, Applicants respectfully submit the present application is fully in condition for allowance. If any issues remain that may be addressed by a phone conversation, the Examiner is invited to contact the undersigned at the phone number listed below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: February 20, 2007

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